Remarks

Claims 3-5 are pending in this application. Claims 3 and 5 have been amended in various particulars as indicated hereinabove. New Claims 6-9 have been added to alternatively define the invention. Claim 4 has been cancelled without prejudice or disclaimer.

Claims 3-5 were rejected under 35 U.S.C. 112, second paragraph.

Applicants believe that the claims as amended are now in compliance with 35 U.S.C. 112, second paragraph. In particular, it has been clarified that the medicament comprises one or more homeopathic dilutions. Illustrative Example 1 in the specification discloses three homeopathic dilutions used in a treatment regimen. Illustrative Example 2 in the specification describes one homeopathic dilution administered to a patient. Illustrative Examples 3 and 4 each describe a medicament comprising three homeopathic dilutions administered to patients.

With regard to Patent Office's objection to the homeopathic terms denoting various dilutions (such a C50, for example), Applicant respectfully brings to the attention of the Patent Office the fact that in the field of homeopathy dilutions are not expressed in terms of metric concentrations, but in terms of decimal (denoted as D or X) or centesimal (denoted as C) dilutions. These are accepted, established and well known designations of dilutions. For example, reference can be made to an authoritative treatise on homeopathy – W. Schwabe,Book of Homeopathic Medication, Berlin 1950 (in German) – which contains an explanation of the decimal and centesimal volumetric dilution scales[1]. As explained in paragraph [0015] of the specification of the present application, a centesimal dilution C means that 1 volumetric part of the original matter (antibodies) is diluted by 99 volumetric parts of a solvent. C12, for example, means twelve consecutive centesimal dilutions as described above. For ultra-low doses of homeopathic preparations only the volumetric dilution designations are used to designate the dilution of various

[1] The decimal and centesimal dilutions are also described in the Homeopathic Pharmacopoeia of the United States (HPUS) http://www.hpus.com . For general reference also refer to: National Institute of Health, National Center for Complementary and Alternative Medicine http://nccam.nih.gov/health/homeopathy/ .

homeopathic preparations[2]. Additionally, the descriptions of what homeopathic technology is and what homeopathic dilutions are can be found in the enclosed with PDF file is a copy of the English language translation of the German Homeopathic Pharmacopoeia (1978, British Homeopathic Association, 5th Supplement of 1991), which has an extensive description of the potentization technique and various types of homeopathic dilutions. Therefore, Applicants respectfully asserts that the use of volumetric designations of the relevant homeopathic dilutions in the present claims is well known, well defined and clear in order to comply with the requirements with 35 U.S.C. 112, second paragraph. Withdrawal of this rejection in view of the amended claim language and the explanation is hereby requested.

Claims 3-5 were rejected under 35 U.S.C. 102(b) over Le *et al.* (US Patent No. 5,698,195). This rejection is respectfully traversed for the following reasons.

It is well established that a claim is anticipated under 35 U.S.C. §102, only if each and every element of the claim is found in a single prior art reference.[3] Moreover, to anticipate a claim under 35 U.S.C. §102, a single source must contain each and every element of the claim "arranged as in the claim."[4, 5] Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference.[6] If each and every element of a claim is not found in a single reference, there can be no anticipation.

Applicants draw the attention of the Patent Office to the dosages in the Le patent cannot be homeopathic dilutions. For example, in Col. 36 lines 16-29 of that patent, the

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[2] Please refer to the same terminology and usage in US Patent 5, 629,286 "*Homeopathic dilutions of growth factors*"; US Patent 5,834,443 "*Composition and method for treating herpes simplex*"; US Patent 7,229,648 "*Homeopathic formulations useful for treating pain and/or inflammation*"; US Patent 6,485,480 "*Treatment methods using homeopathic preparations of growth factors*".

[3] *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

[4] *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

[5] *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q. 2d 1766, 1768 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).

[6] *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985).

lowest dose presented is 0.1 mg per 1 kg of the weight of a patient. Taking an average body weight of a grown adult to be about 70 kg, an administered dose according to the Le patent will be 7 mg, which is a traditional, non-homeopathic, dose. No homeopathic dilution obtained in accordance with the homeopathic technology by series of consecutives centesimal dilutions (such as C12 or C30 disclosed in the Examples) can possibly contain the initial matter (antibodies) in the order of magnitude of several milligrams. In view of the clarification about the meaning of consecutive centesimal dilutions provided above (each subsequent dilution consists of 1 volumetric part of the previous dilution diluted in 99 volumetric parts of the solvent), no dosage disclosed in the Le patent reads or inherently anticipates homeopathic dilutions of potentiated monoclonal or polyclonal antibodies as claimed in amended independent Claim 3 and its dependent Claims.

Withdrawal of the rejection under 35 U.S.C. 102(b) is requested, as well as allowance of amended independent Claim 1 and its dependent Claims.

It is believed that the present application is in condition for allowance. A Notice of Allowance is respectfully solicited. Should any questions arise, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

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MANUFACTURE

Method 1: Mother tinctures and liquid dilutions
Mother tinctures by Method 1 are mixtures of equal parts of expressed juice and ethanol 86 per cent.

Express the finely cut plants or parts of plants, and immediately mix the expressed fluid with an equal part by weight of ethanol 86 per cent. Leave to stand in a closed container for not less than 5 days at a temperature not exceeding 20 °C; filter.

Adjustment to any parameter given in the Monograph
Determine the dry residue or solid content of the above filtrate. Calculate the amount of ethanol 43 per cent (E_1) required, using Formula (1):

$$E_1 = \frac{W\,(N_x - N_0)}{100}\ [kg] \qquad (1)$$

W = weight of filtrate in kg
N_0 = dry residue or solid content in per cent as required by Monograph
N_x = dry residue or solid content of filtrate in per cent.

Combine the filtrate with the required amount of ethanol 43 per cent. Leave to stand at a temperature not exceeding 20 °C for not less than 5 days; filter if necessary.

Potentization
The 1st decimal dilution (1x) is made with
2 parts of the mother tincture and
8 parts of ethanol 43 per cent,

the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 43 per cent.
Subsequent dilutions are produced in the same way.

The 1st centesimal dilution (1c) is made with
2 parts of the mother tincture and
98 parts of ethanol 43 per cent,

the 2nd centesimal dilution (2c) with
1 part of the 1 st centesimal dilution and
99 parts of ethanol 43 per cent.
Subsequent dilutions are produced in the same way.

Method 2a: Mother tinctures and liquid dilutions
Mother tinctures manufactured by Method 2a are produced by macerating the

material as described below (ethanol content approx. 43 per cent).

The plants or parts of plants are finely minced. A sample is used to determine loss on drying. To the minced plant material add immediately not less than half the amount by weight of ethanol 86 per cent and store in well sealed containers at a temperature not exceeding 20 °C.

Calculate the amount of ethanol 86 per cent required (E_2), for the plant material, using Formula (2), deduct the amount of ethanol that has already been used, and add the final amount to the mixture.

$$E_2 = \frac{M \cdot D}{100} \text{ [kg]} \qquad (2)$$

M = weight of plant material in kg
D = loss on drying in sample, in per cent.

Leave the mixture to stand for not less than 10 days at a temperature not exceeding 20 °C, shaking repeatedly. Express and filter.

Adjust to any parameters given in the Monograph, as for Method 1.

Potentize as shown under Method 1.

Method 2b: Mother tinctures and liquid dilutions

Mother tinctures made in accordance with Method 2b are manufactured as per Method 2a, using ethanol 62 per cent (ethanol content approx. 30 per cent).

Use ethanol 30 per cent to adjust to any concentration required in the Monograph.

Potentization

The 1st decimal dilution (1x) is made with
2 parts of the mother tincture and
8 parts of ethanol 30 per cent,

the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 15 per cent.

Subsequent dilutions are produced in the same way.

Method 3a: Mother tinctures and liquid dilutions

Mother tinctures for Method 3a are produced according to Method 2a (ethanol content approx. 60 per cent), with the following difference: The required amount of ethanol 86 per cent (E_3), is calculated according to Formula (3).

$$E_3 = \frac{2 \cdot M \cdot D}{100} \text{ [kg]} \qquad (3)$$

M = weight of plant material in kg
D = loss on drying in sample, in per cent.
Use ethanol 62 per cent to adjust to any concentration required as per Monograph.

Potentization
The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of ethanol 62 per cent,

the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 62 per cent.
Subsequent dilutions are produced in the same way. For dilutions from the 4th decimal onwards use ethanol 43 per cent.

The 1st centesimal dilution (1c) is made with
3 parts of the mother tincture and
97 parts of ethanol 62 per cent,

the 2nd centesimal dilution (2c) with
1 part of the 1st centesimal dilution and
99 parts of ethanol 43 per cent.
Subsequent dilutions are produced in the same way.

Method 3b: Mother tinctures and liquid dilutions
Mother tinctures for Method 3b are produced according to Method 3a, using ethanol 73 per cent (ethanol content approx. 43 per cent).
Use ethanol 43 per cent to adjust to any concentration required in the Monograph.

Potentization
The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of ethanol 43 per cent,

the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 30 per cent,
the 3rd decimal dilution (3x) with
1 part of the 2nd decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

Method 3c: Mother tinctures and liquid dilutions
Mother tinctures for Method 3c are produced according to Method 3a using, ethanol 43 per cent (ethanol content approx. 30 per cent).
Use ethanol 30 per cent to adjust to any concentration required in the Monograph.

Potentization
The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of ethanol 30 per cent,

the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

Method 4a: Mother tinctures and liquid dilutions
Method 4a is for mother tinctures manufactured according to the maceration or percolation methods described in the TINKTUREN (tinctures) Monograph in the German Pharmacopoeia using 1 part of the drug to 10 parts of ethanol in suitable concentration (unless otherwise stated in the Monograph). If adjustment to a given value is necessary, the required amount of ethanol in the concentration prescribed or used for manufacture is calculated according to Formula (1). The calculated amount of ethanol is combined with the filtrate. The mixture is left to stand for not less than five days at a temperature not exceeding 20 °C, after which it is filtered if required.

Potentization
The mother tincture is equivalent to the 1st decimal dilution (ø = 1x).

The 2nd decimal dilution (2x) is made with
1 part of the mother tincture and
9 parts of ethanol of the same concentration.

the 3rd decimal dilution (3x) with
1 part of the 2nd decimal dilution and
9 parts of ethanol of the same concentration.
Ethanol 43 per cent is used for subsequent dilutions from the 4th decimal upwards unless a different concentration is prescribed; the method is the same as for the 3rd decimal dilution.

The 1st centesimal dilution (1c) is made with
10 parts of the mother tincture and
90 parts of ethanol of the same concentration.

the 2nd centesimal dilution (2c) with
1 part of the 1st centesimal dilution and
99 parts of ethanol 43 per cent, unless another concentration is prescribed.
Subsequent dilutions are produced in the same way.

Method 4b: Mother tinctures and liquid dilutions
Method 4b is for mother tinctures manufactured according to the maceration or

percolation methods described in the TINKTUREN (tinctures) Monograph in the German Pharmacopoeia using 1 part of animals, parts of animals or animal secretions and 10 parts of ethanol in suitable concentration. If adjustment to a given value is necessary, the required amount of ethanol in the concentration prescribed or used for manufacture is calculated according to Formula (1). The calculated amount of ethanol is combined with the filtrate. The mixture is left to stand for not less than five days at a temperature not exceeding 20 °C, after which it is filtered if required.

Potentization
The mother tincture is equivalent to the 1st decimal dilution (ø = 1x).

The 2nd decimal dilution (2x) is made with
1 part of the mother tincture and
9 parts of ethanol of the same concentration.

the 3rd decimal dilution (3x) with
1 part of the 2nd decimal dilution and
9 parts of ethanol of the same concentration.
Ethanol 43 per cent is used for subsequent dilutions from the 4th decimal upwards; the method is the same as for the 3rd decimal dilution.

The 1st centesimal dilution (1c) is made with
10 parts of the mother tincture and
90 parts of ethanol of the same concentration.

the 2nd centesimal dilution (2c) with
1 part of the 1st centesimal dilution and
99 parts of ethanol 43 per cent.
Subsequent dilutions are produced in the same way.

Method 5a: Solutions
Liquid preparations made by Method 5a are solutions produced from basic drug materials and a liquid vehicle. Unless otherwise prescribed in the Monograph, 1 part of the basic drug material is dissolved in 9 parts (= 1x) or 99 parts (= 1c or 2x) of the liquid vehicle and succussed. Absolute ethanol, purified water, glycerol 85 per cent and the ethanol/water mixtures listed in the GHP are used as vehicles.

If ethanol 15 per cent is the prescribed vehicle for the liquid preparation, the solution may also be produced by the following method: 1 part of the basic drug material is dissolved in 7.58 parts of water, to produce the 1x; add 1.42 parts of ethanol to the solution. To produce the 1c or 2x, 1 part of the basic drug material is dissolved in 83.4 parts of water, adding 15.6 parts of ethanol to the solution.

Potentization
The 2nd decimal dilution (2x) is made with
1 part of the mother tincture and
9 parts of ethanol 43 per cent,

unless another vehicle is prescribed. Subsequent dilutions are produced in the same way.

The 2nd centesimal dilution (2c) is made with
1 part of the 1st centesimal dilution (1c) and
99 parts of ethanol 43 per cent,
unless another liquid vehicle is prescribed. Subsequent dilutions are produced in the same way.

Method 5b: Aqueous solutions
Liquid preparations made by Method 5b are solutions produced from basic drug materials and WATER FOR INJECTIONS. Unless otherwise stated in the Monograph, 1 part of the basic drug material is dissolved in 9 parts (= 1x) or 99 parts (= 1c or 2x) of WATER FOR INJECTIONS and succussed.

Potentization
The 2nd decimal dilution (2x) is made with
1 part of the solution (1x) and
9 parts of WATER FOR INJECTIONS.
Subsequent dilutions are produced in the same way.

Aqueous solutions produced by Method 5b are normally processed immediately; their use is limited to the manufacture of preparations by Methods 11, 13, 14, 15, 39a and 39c.

Solutions made according to Method 5b and their liquid dilutions must comply with the 'Sterility Test' given in the German Pharmacopoeia if stored.

LABELLING
Preparations made according to Method 5b carry the designation 'aquos.' after the indication of the potency; the same applies to presentations made from them.

Method 6: Triturations
Preparations made according to Method 6 are triturations of solid basic drug materials with lactose as the vehicle unless otherwise prescribed. Triturations up to and including the 4th dilution are triturated by hand or machine in a ratio of 1 to 10 (decimal dilution) or 1 to 100 (centesimal dilution). Unless otherwise stated, the basic drug materials are reduced to the particle size given in the Monograph (mesh aperture). Quantities of more than 1,000 g are triturated by mechanical means.

The duration and intensity of trituration should be such that the resulting particle size of the basic drug material in the 1st decimal or centesimal dilution is below 10 μm at 80 per cent level; no drug particle should be more than 50 μm.

Triturations up to and including the 4th decimal or centesimal are produced at the same duration and intensity of trituration.

Trituration by hand
Divide the vehicle into three parts and triturate the first part for a short period in a porcelain mortar. Add the basic drug material and triturate for 6 minutes, scrape

down for 4 minutes with a porcelain spatula, triturate for a further 6 minutes, scrape down again for 4 minutes, add the second part of the vehicle and continue as above. Finally add the third part and proceed as before. The minimum time required for the whole process will thus be 1 hour. The same method is followed for subsequent dilutions.

For triturations above the 4x or 4c dilute 1 part of the dilution with 9 parts of lactose or 99 parts of lactose as follows: in a mortar, combine one third of the required amount of lactose with the whole of the previous dilution and mix until homogeneous. Add the second third of the lactose, mix until homogeneous, and repeat for the last third.

Trituration by machine

Up to and including the 4th dilution, triturations are made in a machine fitted with a scraping device that ensures even trituration.

Other machines may be used, providing the particle sizes produced meet requirements.

To produce a trituration by machine, triturate one third of the vehicle, add the basic drug material and triturate; finally add the remaining vehicle in two equal portions and triturate. The time required to produce one trituration by machine is not less than 1 hour.

Dilutions above the 4x or 4c are made by diluting 1 part of the dilution with 9 parts of lactose or 99 parts of lactose and combining one third of the required amount of lactose in a suitable mixer with the whole of the previous dilution and mixing until homogeneous. Add the second third of the lactose, mix until homogeneous, and proceed in the same way with the last third of the lactose.

The choice of a suitable mixer and the mixing time required to achieve homogeneity are established in a single trial run for each type of apparatus and recorded. Additional requirements relating to the machine in question are determined, recorded and written down in the operating instructions for the production process.

Method 7: Triturations

Preparations made by Method 7 are solid preparations of mother tinctures and solutions and their dilutions with lactose as the vehicle.

The total amount of lactose required is transferred to a suitable apparatus, and the prescribed amount of the liquid preparation in the previous dilution stage is gradually mixed in. The moist homogeneous mix is dried with care, ground if necessary and sieved before mixing again thoroughly.

The amount of lactose used should be such that the preparation will have the prescribed total weight when the manufacturing process is complete.

Quantities of more than 1,000 g are made by mechanical trituration; the type of mixer, mixing period, drying time and length of the final mixing stage are determined in a single trial run, recorded and written down in the operating instructions for the production process.

Potentization

Mother tinctures, solutions and liquid dilutions are potentized in the relative

quantities laid down for their production. Lactose serves as the vehicle; the amount of lactose added must be such that the total weight is 10 parts for decimal and 100 parts for centesimal potencies.

Method 8a: Liquid preparations made from triturations
Preparations made by Method 8a are liquid preparations produced from triturations made by Method 6.

To produce a 6x liquid dilution, 1 part of the 4x trituration is dissolved in 9 parts of water and succussed. 1 part of this dilution is combined with 9 parts of ethanol 30 per cent to produce the 6x liquid dilution by succussion. In the same way, the 7x liquid dilution is made from the 5x trituration, and the 8x liquid dilution from the 6x trituration. From the 9x upwards, liquid decimal dilutions are made from the previous decimal dilution with ethanol 43 per cent in a ratio of 1 to 10.

To produce a 6c liquid dilution, 1 part of the 4c trituration is dissolved in 99 parts of water and succussed. 1 part of this dilution is combined with 99 parts of ethanol 30 per cent to produce the 6c liquid dilution by succussion. In the same way, the 7c liquid dilution is made from the 5c trituration, and the 8c liquid dilution from the 6c trituration. From the 9c upwards, liquid centesimal dilutions are made from the previous centesimal dilution with ethanol 43 per cent in a ratio of 1 to 100.

The 6x, 7x, 6c and 7c liquid dilutions produced by the above method must not be used to produce further liquid dilutions.

Method 8b: Aqueous preparations made from triturations
Preparations made by Method 8b are aqueous preparations produced from triturations made by Method 6.

To produce a 6x liquid dilution, 1 part of the 4x trituration is dissolved in 9 parts of WATER FOR INJECTIONS and succussed. 1 part of this dilution is combined with 9 parts of WATER FOR INJECTIONS to produce the 6x liquid dilution by succussion. In the same way, the 7x liquid dilution is made from the 5x trituration, and the 8x liquid dilution from the 6x trituration. From the 9x upwards, liquid decimal dilutions are made from the previous decimal dilution with WATER FOR INJECTIONS in a ratio of 1 to 10.

6x and 7x liquid dilutions made by the above method must not be used to produce further liquid dilutions.

Aqueous preparations made by Method 8b are normally processed immediately; their use is limited to the manufacture of presentations by Methods 11, 13, 14, 15, 39a and 39c, mixtures by Method 16, and potentized mixtures by Method 40b.

Aqueous preparations made by Method 8b must comply with the 'Sterility Test' of the German Pharmacopoeia if stored.

LABELLING
Preparations made by Method 8b carry the designation 'aquos.' after the indication of the potency; the same applies to presentations made from them.

Method 9: Tablets
Tablets made by Method 9 are produced from preparations made by Method 6 or

Method 7.

Except for 'Uniformity of content' they must comply with the **Tablets** monograph for uncoated tablets in the German Pharmacopoeia.

Permitted excipients are starch—in concentrations of up to 10 per cent—and calcium behenate or magnesium stearate—in concentrations of up to 2 per cent. A saturated lactose solution or starch paste or ethanol in suitable concentration is used if granulation is required.

Tablets prepared solely from preparations produced by Method 6 or 7 are single doses containing 100 or 250 mg of the particular preparation. The weight of excipients is additional to this.

LABELLING

Tablets are labelled with the dilution stage in accord with preparation by Method 6 or 7.

Method 10: Granules (Globuli)

Preparations made by Method 10 are granules (globuli). They are produced by transferring a dilution to sucrose granules (size 3: 110-130 granules weigh 1 g) by moistening 100 parts of sucrose granules evenly with 1 part of dilution. The ethanol content of the dilution should be not less than 60 per cent. If this is not the case, it will be necessary to go against Methods 1 to 4b and produce the final potentization of the decimal or centesimal dilution which is to be used with ethanol 62 per cent.

Following impregnation in a closed vessel, the granules (globuli) are air-dried. They are labelled with the dilution stage of the dilution used to impregnate them.

The following granule sizes may be used in special cases:

Size 1	470-530	granules weigh 1 g
Size 2	220-280	granules weigh 1 g
Size 3	110-130	granules weigh 1 g
Size 4	70- 90	granules weigh 1 g
Size 5	40- 50	granules weigh 1 g
Size 6	22- 28	granules weigh 1 g
Size 7	10	granules weigh approx. 1 g
Size 8	5	granules weigh approx. 1 g
Size 9	3	granules weigh approx. 1 g
Size 10	2	granules weigh approx. 1 g

Method 11: Parenteral preparations

Preparations made by Method 11 are sterile, injectable dilutions of one or more homoeopathic preparations. They are designed for injection and must comply with the **Parenteralia** monograph in the German Pharmacopoeia. The only additives permitted are agents used to make the preparations isotonic and adjust the pH; preservatives may be used in specific cases. Sodium chloride is normally used to make preparations isotonic; other agents used for that purpose must be declared.

Parenteral preparations for human use are supplied in single-dose glass ampoules. Multi-dose glass containers may be used for veterinary preparations.

'Uniformity of content' tests (V.5.2.2) are not required.

With parenteral preparations produced from preparations containing ethanol, care is taken to keep the final ethanol content as low as possible.

This may be achieved by mixing and/or potentizing with water for injections or the solution of isotonizing agent. For potentization, an ethanol-free vehicle is used for the last two decimal dilution stages and the last centesimal dilution stage respectively.

LABELLING

Different potencies combined for further potentization must be stated. Added vehicles must be stated.

Method 12a: Liquid external applications

Preparations made by Method 12a are tinctures for external use produced as follows:

using mother tinctures made by Method 1 or 2a or 19a, combine
2 parts of the mother tincture with
3 parts of ethanol 43 per cent,

using mother tinctures made by Method 2b or 19b, combine
2 parts of the mother tincture with
3 parts of ethanol 30 per cent,

using mother tinctures made by Method 3a or 19c, combine
3 parts of the mother tincture with
2 parts of ethanol 62 per cent,

using mother tinctures made by Method 3b or 19d, combine
3 parts of the mother tincture with
2 parts of ethanol 43 per cent,

using mother tinctures made by Method 3c or 19e, combine
3 parts of the mother tincture with
2 parts of ethanol 30 per cent,

using mother tinctures made by Method 4a or 4b or 19f, combine
1 part of the mother tincture with
1 part of ethanol in the concentration used to make the mother tincture;

by extracting dried plants or parts of plants with ethanol in a ratio of 1 :5 (as per Method 4a or 19f).

Tinctures for external use may contain up to 10 per cent of glycerin as an additive.

NOTE

Tinctures for external use are not for internal use and are labelled to indicate this.

Method 12b: Liquid external applications
Preparations made by Method 12b are tinctures for external use produced by Method 2a with ethanol 73 per cent.

The Method differs from Method 2a in that the amount of ethanol 73 per cent required (E) is calculated using the following formula:

$$E = \frac{4 \cdot Mm \cdot D}{100} \quad [kg]$$

M = weight of plant material in kg
D = loss on drying in sample, in per cent.

LABELLING
Preparations made by Method 12b are labelled 'ad usum externum'.

Method 12c: Liquid external applications
Preparations made by Method 12c are tinctures for external use produced by maceration according to the following method:

Finely mince the plants or parts of plants, unless flowers only are used. Use a sample to determine loss on drying. To 1 part of the plant material add immediately 2.88 parts of water and 1.12 parts of ethanol and store at a temperature not exceeding 20 °C. The additional amount of water (W) required is calculated according to the formula:

$$W = \frac{M \cdot (100 - D)}{100} \quad [kg]$$

M = weight of plant material in kg
D = loss on drying in sample, in per cent,
and added to the mixture. Leave to stand for not less than 5 days at a temperature not exceeding 20 °C; stir the mixture every morning and evening during those 5 days. Express and filter.

LABELLING
Preparations made by Method 12c are labelled 'LE 20%'.

STORAGE
Protected from light.

Method 12d: Liquid external applications
Preparations made by Method 12d are oils for external use produced with 1 part of the dried plants or parts of plants and 10 parts of vegetable oil, using the method given below. Groundnut oil, olive oil or sesame oil are normally used; other oils

must be declared.

Moisten 1 part of the minced drug with 0.25 parts of ethanol. Cover and leave to stand for approx. 12 hours before combining with 10 parts of vegetable oil. Heat the mixture to 60 - 70 °C and maintain it at that temperature for approx. 4 hours. Express and filter.

LABELLING
Preparations made by Method 12d are labelled 'H 10%'.

STORAGE
Protected from light, in sealed containers, as far as possible full ones.

Method 12e: Liquid external applications
Preparations made by Method 12e are oils for external use produced with 1 part of the dried plants or parts of plants and 20 parts of vegetable oil, using the method given below. Groundnut oil, olive oil or sesame oil are normally used; other oils must be declared.

Moisten 1 part of the minced drug with 0.25 parts of ethanol. Cover and leave to stand for approx. 12 hours before combining with 20 parts of vegetable oil. Heat the mixture to 60 - 70 °C and maintain it at that temperature for approx. 4 hours. Express and filter.

LABELLING
Preparations made by Method 12e are labelled 'H 5%'.

STORAGE
Protected from light, in sealed containers, as far as possible full ones.

Method 12f: Liquid external applications
Preparations made by Method 12f are oils for external use produced with 1 part of the dried plants or parts of plants and 10 parts of vegetable oil, using the method given below. Groundnut oil, olive oil or sesame oil are normally used; other oils must be declared.

Combine 1 part of the minced drug with 10 parts of vegetable oil. Heat under CARBON DIOXIDE to approx. 37 °C and maintain at that temperature for 7 days; during that time, the mixture is stirred for 5 minutes every morning and evening, with the vessel kept closed. Express and filter.

LABELLING
Preparations made by Method 12f are labelled 'W 10%'.

STORAGE
Protected from light, in sealed containers, as far as possible full ones.

Method 12g: Liquid external applications
Preparations made by Method 12g are oils for external use produced with 1 part of the dried plants or parts of plants and 20 parts of vegetable oil, using the method

given below. Groundnut oil, olive oil or sesame oil are normally used; other oils must be declared.

Combine 1 part of the minced drug with 20 parts of vegetable oil. Heat under CARBON DIOXIDE to approx. 37,°C and maintain at that temperature for 7 days; during that time, the mixture is stirred for 5 minutes every morning and evening, with the vessel kept closed. Express and filter.

LABELLING
Preparations made by Method 12g are labelled 'W 5%'.

STORAGE
Protected from light, in sealed containers, as far as possible full ones.

Method 12h: Liquid external applications
Preparations made by Method 12h are oils for external use produced by mixing 1 part of an essential oil with 9 parts of vegetable oil. Groundnut oil, olive oil or sesame oil are normally used; other oils must be declared.

LABELLING
Preparations made by Method 12h are labelled '10%'.

STORAGE
Protected from light, in sealed containers, as far as possible full ones.

Method 12i: Liquid external applications
Preparations made by Method 12i are oils for external use produced by mixing 1 part of an essential oil with 19 parts of vegetable oil. Groundnut oil, olive oil or sesame oil are normally used; other oils must be declared.

LABELLING
Preparations made by Method 12i are labelled '5%'.

STORAGE
Protected from light, in sealed containers, as far as possible full ones.

Method 12j: Liquid external applications
Liquid external applications made by Method 12j are oily preparations for external use made from liquid dilutions.

To produce an oily dilution 3x, 1 part of liquid dilution 1x is succussed with 9 parts of anhydrous ethanol. 1 part of this dilution is treated in the same way to produce liquid dilution 3x. 1 part of liquid dilution 3x is mixed with 99 parts of vegetable oil.

The same method is used to produce oily dilution 4x from liquid dilution 2x, and oily dilutions from the 5x onwards. Olive oil is normally used; other oils must be declared.

LABELLING
Liquid external applications made by Method 12j are labelled 'oleos'.

Method 12k: Liquid external applications
Preparations made by Method 12k are tinctures for external use. They are made by the following method.

Fresh plants or parts of plants are finely minced. Loss on drying is determined on a sample. 1 part of plant material is immediately combined with three parts of water and heated to boiling for 30 minutes; water lost by evaporation is replaced. After this, 3.76 parts of water and 2.24 parts of ethanol 96 per cent are added. The additional amount of water required (W) is calculated as for Method 12c and added to the mixture. Leave to stand for not less than 5 days at a temperature not exceeding 20 °C; stir the mixture every morning and evening during those 5 days. Express and filter.

LABELLING
Liquid external applications made by Method 12k are labelled 'decoctum LE 10%'.

STORAGE
Protected from light.

Method 13: Ointments
Preparations made by Method 13 are made from one or more homoeopathic preparations in a suitable basis, usually wool alcohols ointment basis. Other bases must be declared.

Ointments must comply with the **Salben** monograph of the German Pharmacopoeia.

Not permitted are auxiliary substances such as antioxidants, stabilizers and—except in the case of hydrous gels and oil-in-water emulsions—preservatives.

LABELLING
Ointments containing the homoeopathic preparation in a ratio of 1 : 10 in the case of mother tinctures and decimal dilutions and of 1 : 100 in the case of centesimal dilutions are labelled with the homoeopathic preparation used.

Method 14: Suppositories
Preparations made by Method 14 are made from one or more homoeopathic preparations and a suitable basis. Hard fat is normally used as the basis; other bases must be declared.

Suppositories must comply with the requirements of the **Suppositorien** monograph in the German Pharmacopoeia. Additions other than the excipients listed under that heading in the *GHP* are not permitted.

'Uniformity of content' tests (V.5.2.2) are not required.

LABELLING
Suppositories containing the homoeopathic preparation in a ratio of 1 : 10 in the case of mother tinctures and decimal dilutions and of 1 : 100 in the case of centesimal dilutions are labelled with the homoeopathic preparation used.

Method 15: Eye drops

Eyes drops made by Method 15 are sterile aqueous fluids with a residual ethanol content of not more than one per cent.

They are produced from one or more homoeopathic preparations and comply with the requirements of the **Augentropfen** (eye drops) monograph in the German Pharmacopoeia.

They contain no additives except for preservatives and agents used to make the isotonic and adjust the pH.

To manufacture the eye drops, use water for injections or the solution of the isotonizing agent, normally sodium chloride, to produce the last two decimal dilutions and the last centesimal dilution respectively; other isotonizing agents must be declared. Ethanol-free drug vehicles may also be added.

LABELLING

State potency stages that have combined before being taken to higher potency stages; state drug vehicles if added.

Method 16: Mixtures

Preparations made by Method 16 are

1) Liquid and/or solid preparations in which the vehicle has been added in a proportion other than 1 to 10 or 1 to 100,
2) mixtures of liquid and/or solid preparations,
3) mixtures of liquid and/or solid preparations to which vehicles and/or auxiliary substances have been added.

All types of presentations may be produced from the above mixtures. Mixtures containing LIQUEUR WINE and/or preparations made by Method 46 must not be processed further.

Liquid external applications are manufactured as mixtures of preparations made by Methods 12a-i.

LABELLING

Composition is shown in such a way that the nature and amount of basic drug materials and of liquid and/or solid preparations incorporated in the mixture is clearly apparent. LIQUEUR WINE used in the production of vehicles must be declared on the container.

Method 17: LM potencies

To produce a LM I potency, dissolve 60 mg of a 3c trituration of the substance to be potentized in 20.0 ml of ethanol 15 per cent (= 500 drops). Transfer 1 drop of the solution to a small vial, add 2.5 ml of ethanol 86 per cent (= 100 drops) and shake vigorously 100 times. Moisten 100 g of size 1 granules (approx. 50,000 granules) evenly with the solution; following impregnation in a closed container the granules are air-dried. They represent the LM I potency.

To produce the LM II potency, transfer 1 granule of the LM I potency to a small vial and dissolve in 1 drop of water; add 2.5 ml of ethanol 86 per cent (= 100 drops) and shake vigorously 100 times. Moisten 100 g size 1 granules (approx. 50,000 granules) evenly with the solution; following impregnation in a closed container

the granules are air-dried.

Higher potencies are produced by the same method.

To produce liquid LM potencies, dissolve 1 granule of the required potency in 10.0 ml of ethanol 15 per cent. The solution is the same potency as the granule dissolved in it.

Method 18a: Heat-treated mother tinctures and liquid dilutions of these

Mother tinctures made by Method 18a are produced like mother tinctures made by Method 2a and heat-treated.

The mixture containing the total amount of ethanol 86 per cent required is heated to 37 °C in a covered container and maintained at that temperature for one hour, stirring occasionally. After cooling the mixture is processed as under Method 2a.

Potentization

The 1st decimal dilution (1x) is made with
2 parts of the mother tincture and
8 parts of ethanol 43 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 30 per cent.
The 3rd decimal dilution (3x) is made with
1 part of the 2nd decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING

Preparations made by Method 18a are labelled 'ethanol. digested'; the same applies to presentations made from them.

Method 18b: Heat-treated mother tinctures and liquid dilutions of these

Mother tinctures made by Method 18b are produced like mother tinctures made by Method 2b and heat-treated.

The mixture containing the total amount of ethanol 62 per cent required is heated to 37 °C in a covered container and maintained at that temperature for one hour, stirring occasionally. After cooling the mixture is processed as under Method 2a. Use ethanol 30 per cent to adjust to any value required by the Monograph.

Potentization

The 1st decimal dilution (1x) is made with
2 parts of the mother tincture and
8 parts of ethanol 30 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 18b are labelled 'ethanol. digested'; the same applies to presentations made from them.

Method 18c: Heat-treated mother tinctures and liquid dilutions of these
Mother tinctures made by Method 18c are produced like mother tinctures made by Method 3a and heat-treated.

The mixture containing the total amount of ethanol 86 per cent required is heated to 37 °C in a covered container and maintained at that temperature for one hour, stirring occasionally. After cooling the mixture is processed as under Method 2a. Use ethanol 62 per cent to adjust to any value required by the Monograph.

Potentization
The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of ethanol 62 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 43 per cent.
The 3rd decimal dilution (3x) is made with
1 part of the 2nd decimal dilution and
9 parts of ethanol 30 per cent,
The 4th decimal dilution (4x) is made with
1 part of the 3rd decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 18c are labelled 'ethanol. digested'; the same applies to presentations made from them.

Method 18d: Heat-treated mother tinctures and liquid dilutions of these
Mother tinctures made by Method 18d are produced like mother tinctures made by Method 3b and heat-treated.

The mixture containing the total amount of ethanol 73 per cent required is heated to 37 °C in a covered container and maintained at that temperature for one hour, stirring occasionally. After cooling the mixture is processed as under Method 2a. Use ethanol 43 per cent to adjust to any value required by Monograph.

Potentization
The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of ethanol 43 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 30 per cent.
The 3rd decimal dilution (3x) is made with

1 part of the 2nd decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 18d are labelled 'ethanol. digested'; the same applies to presentations made from them.

Method 18e: Heat-treated mother tinctures and liquid dilutions of these
Mother tinctures made by Method 18e are produced like mother tinctures made by Method 3c and heat-treated.

The mixture containing the total amount of ethanol 43 per cent required is heated to 37 °C in a covered container and maintained at that temperature for one hour, stirring occasionally. After cooling the mixture is processed as under Method 2a. Use ethanol 30 per cent to adjust to any value required by Monograph.

Potentization
The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of ethanol 30 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 18e are labelled 'ethanol. digested'; the same applies to presentations made from them.

Method 18f: Heat-treated mother tinctures and liquid dilutions of these
Mother tinctures made by Method 18f are produced like mother tinctures made by Method 4a and heat-treated.

The mixture containing the total amount of ethanol 43 in the given concentration is heated to 37 °C in a covered container and maintained at that temperature for one hour, stirring occasionally. After cooling the mixture is macerated as per the TINCTURES Monograph in the Pharmacopoeia and then processed as under Method 4a.

Potentization
The mother tincture is equivalent to the 1st decimal dilution (ø = 1x).
the 2nd decimal dilution (2x) is made with
1 part of the mother tincture
9 parts of ethanol of the same concentration.

Subsequent decimal dilutions are produced in the same way, reducing the ethanol concentration stage by stage in the sequence 94 - 86 - 73 - 62 - 43 - 30 - 15 per cent until an ethanol concentration of 15 per cent is reached.

LABELLING
Preparations made by Method 18f are labelled 'ethanol. digested'; the same applies to presentations made from them.

Method 19a: Heat-treated mother tinctures and liquid preparations made from these
Mother tinctures made by Method 19a are produced by maceration using the procedure given below.

Prepare the mixture as per Method 2a, adding the total amount of ethanol 86 per cent required. Heat under reflux to boiling and maintain at boiling temperature for 30 minutes. Allow to cool and leave to stand in a closed container for 24 hours; express and filter.

Adjust to any value given in the Monograph by the method given under Method 1.

Potentization
The 1st decimal dilution (1x) is made with
2 parts of the mother tincture and
8 parts of ethanol 43 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 30 per cent.
The 3rd decimal dilution (3x) is made with
1 part of the 2nd decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 19a are labelled 'ethanol. decoct.'; the same applies to presentations made from them.

Method 19b: Heat-treated mother tinctures and liquid preparations made from these
Mother tinctures made by Method 19b are produced by maceration using the procedure given below.

Prepare the mixture as per Method 2b, adding the total amount of ethanol 62 per cent required. Heat under reflux to boiling and maintain at boiling temperature for 30 minutes. Allow to cool and leave to stand in a closed container for 24 hours; express and filter.

Adjust to any value given in the Monograph using ethanol 30 per cent.

Potentization
The 1st decimal dilution (1x) is made with
2 parts of the mother tincture and
8 parts of ethanol 30 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and

9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 19b are labelled 'ethanol. decoct.'; the same applies to presentations made from them.

Method 19c: Heat-treated mother tinctures and liquid preparations made from these
Mother tinctures made by Method 19c are produced by maceration using the procedure given below.

Prepare the mixture as per Method 3a, adding the total amount of ethanol 86 per cent required. Heat under reflux to boiling and maintain at boiling temperature for 30 minutes. Allow to cool and leave to stand in a closed container for 24 hours; express and filter.

Adjust to any value given in the Monograph using ethanol 62 per cent.

Potentization
The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of ethanol 62 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 43 per cent.
the 3rd decimal dilution (3x) with
1 part of the 2nd decimal dilution and
9 parts of ethanol 30 per cent,
the 4th decimal dilution (4x) with
1 part of the 3rd decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 19c are labelled 'ethanol. decoct.'; the same applies to presentations made from them.

Method 19d: Heat-treated mother tinctures and liquid preparations made from these
Mother tinctures made by Method 19d are produced by maceration using the procedure given below.

Prepare the mixture as per Method 3b, adding the total amount of ethanol 73 per cent required. Heat under reflux to boiling and maintain at boiling temperature for 30 minutes. Allow to cool and leave to stand in a closed container for 24 hours; express and filter.

Adjust to any value given in the Monograph using ethanol 43 per cent.

Potentization
The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of ethanol 43 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 30 per cent,
the 3rd decimal dilution (3x) with
1 part of the 2nd decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 19d are labelled 'ethanol. decoct.'; the same applies to presentations made from them.

Method 19e: Heat-treated mother tinctures and liquid preparations made from these
Mother tinctures made by Method 19e are produced by maceration using the procedure given below.

Prepare the mixture as per Method 3c, adding the total amount of ethanol 43 per cent required. Heat under reflux to boiling and maintain at boiling temperature for 30 minutes. Allow to cool and leave to stand in a closed container for 24 hours; express and filter.

Adjust to any value given in the Monograph using ethanol 30 per cent.

Potentization
The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of ethanol 30 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 19e are labelled 'ethanol. decoct.'; the same applies to presentations made from them.

Method 19f: Heat-treated mother tinctures and liquid preparations made from these
Mother tinctures made by Method 19f are produced by maceration using the procedure given below.

Prepare the mixture as per Method 4a, adding the total amount of ethanol in the required concentration: Heat under reflux to boiling and maintain at boiling temperature for 30 minutes. Allow to cool and leave to stand in a closed container for 24 hours; express and filter.

Adjust to any value given in the Monograph by the method given under Method 4a.

Potentization

The mother tincture is equivalent to the 1st decimal dilution (ø = 1x).

The 2nd decimal dilution (2x) is made with

1 part of the mother tincture and

9 parts of ethanol of the same concentration.

Subsequent dilutions are produced in the same way, reducing the ethanol concentration stage by stage in the sequence 94 - 86 - 73 - 62 - 43 - 30 - 15 per cent until an ethanol concentration of 15 per cent is reached.

LABELLING

Preparations made by Method 19f are labelled 'ethanol. decoct.'; the same applies to presentations made from them.

Method 20: Heat-treated mother tinctures and liquid dilutions made from these Mother tinctures made by Method 20 are produced from dried plants or parts of plants, using 1 part of the plant drug to 10 parts of ethanol of a suitable concentration and following the procedure given below. The quantities of ethanol and water required to achieve the prescribed concentration are added separately.

Add the total amount of ethanol to the minced plant drug (710 μm), cover, and leave to stand for 15 minutes. Add the water, heated to boiling, and keep the mixture at boiling point under reflux for 5 minutes. Allow to cool and then leave to stand in a closed container for 24 hours; express and filter.

Potentization

The mother tincture is equivalent to the 1st decimal dilution (ø = 1x)

The 2nd decimal dilution (2x) is made with

1 part of the mother tincture

9 parts of ethanol of the same concentration.

Subsequent dilutions are produced in the same way, reducing the ethanol concentration stage by stage in the sequence 94 - 86 - 73 - 62 - 43 - 30 - 15 per cent until an ethanol concentration of 15 per cent is reached.

LABELLING

Preparations made by Method 20 are labelled 'ethanol. infusion'; the same applies to presentations made from them.

Method 21: Rh mother tinctures and liquid dilutions made from these Rh mother tinctures made by Method 21 are produced from fresh plants that yield at least 50 per cent of expressed fluid; no vehicle is added.

The plants are minced and expressed immediately on harvesting. The expressed fluid is transferred to containers that are no more than one quarter full and exposed to the diurnal temperature changes ('Rh') described below.

In the morning, bring the expressed fluid to a temperature of approx. 37 °C over a period of at least 30 minutes and maintain at this temperature until evening, when the temperature is reduced to approx. 4 °C over a period of at least 30

minutes; the fluid is maintained at that temperature over night.
Shake the container for at least 10 minutes during each temperature phase.
Filter as soon as fermentation has ceased.

Potentization
The first decimal dilution (1x) is made with
1 part of the Rh mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way; 'Water for Injections' is the vehicle used for all dilutions.
Transfer the dilutions immediately to containers with a maximum capacity of 20 ml. Heat to 70 °C and maintain at that temperature for 1 hour on three consecutive days, maintaining them at room temperature in the interim periods.

LABELLING
Preparations made by Method 21 are labelled 'Rh'; the same applies to presentations made from them.

STORAGE
Rh mother tinctures are stored in tightly sealed containers and protected from light.

Method 22: Rh mother tinctures and liquid dilutions made from these
Rh mother tinctures made by Method 22 are produced from fresh plants that yield less than 50 per cent of expressed fluid; no vehicle is added.
The plants are minced immediately on harvesting. The minced plant material is exposed to the diurnal temperature change ('Rh') which is described under Method 21 for approx. 10 days and then expressed.
The expressed fluid is treated as per Method 21 until fermentation is complete.
Filter as soon as fermentation has ceased.

Potentization
The first decimal dilution (1x) is made with
1 part of the Rh mother tincture and
9 parts of water for injections.
Proceed in the same manner for subsequent dilutions; 'Water for Injections' is the vehicle used for all dilutions.
Transfer the dilutions immediately to containers with a maximum capacity of 20 ml. Heat to 70 °C and maintain at that temperature for 1 hour on three consecutive days, maintaining them at room temperature in the interim periods.

LABELLING
Preparations made by Method 22 are labelled 'Rh'; the same applies to presentations made from them.

STORAGE
Rh mother tinctures are stored in tightly sealed containers and protected from

light.

Method 23: Heat-treated aqueous mother tinctures and liquid dilutions made from these.

Aqueous mother tinctures made by Method 23 are produced from 1 part of minced plant drug and 10 parts of water, following the procedure given below.

Combine 1 part of the minced plant drug with 10 parts of water at a temperature of over 90 °C, place on a water bath and maintain at that temperature for 30 minutes, stirring repeatedly. Filter hot. If gentle pressure applied to the drug residue does not achieve a final weight of mother tincture equal to 10 parts, pour a sufficient amount of boiling water over the drug residue and express gently. Use the resulting extract to make up the final weight.

Potentization

The mother tincture is equivalent to the 1st decimal dilution (ø= 1x)

The 2nd decimal dilution (2x) is made with

1 part of the mother tincture and

9 parts of water for injections.

Proceed in the same manner for subsequent dilutions.

Aqueous mother tinctures made by Method 23 are normally processed immediately; they are used exclusively to produce 'Liquid dilutions for injection' by Method 11 and 'Eye drops' by Method 15, or in mixtures according to Method 16.

Aqueous mother tinctures made by Method 23 and their liquid dilutions must comply with the 'Test for sterility' of the German Pharmacopoeia if stored for further processing.

LABELLING

Preparations made by Method 23 are labelled 'Decoct.'; the same applies to presentations made from them.

Method 23b: Heat-treated aqueous mother tinctures and liquid dilutions made from these.

Aqueous other tinctures made by Method 23b are made from fresh plants or parts of plants by the method given below.

Before processing the plant material, determine loss on drying on a sample. Calculate the amount of water (W) required with the aid of the following formula:

$$W = \frac{M \cdot (300 - D)}{100} \text{ [kg]}$$

M = weight of plant material in kg

D = loss on drying in per cent

Heat the calculated amount of water to a temperature of over 90 °C and add the minced plant material. Maintain at that temperature for 30 minutes under reflux, stirring repeatedly. Express and filter.

The 1st decimal dilution (1x) is made with
3 parts of the mother tincture and
7 parts of water for injections,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.

Aqueous mother tinctures made by Method 23b are normally processed immediately; they are used exclusively to produce 'Liquid dilutions for injection' by Method 11 and 'Eye drops' by Method 15.

Aqueous mother tinctures made by Method 23b and their liquid dilutions must comply with the 'Test for sterility' of the German Pharmacopoeia if stored for further processing.

LABELLING
Preparations made by Method 23b are labelled 'Decoct.'; the same applies to presentations made from them.

Method 24: Heat-treated aqueous mother tinctures and liquid dilutions made from these
Aqueous mother tinctures made by Method 24 are produced from 1 part of minced plant drug and 10 parts of water, following the procedure given below.

Combine 1 part of the minced plant drug in a mortar with 3 - 5 times the amount of water, knead through a number of times and leave to stand for 15 minutes. After this period add the remaining water which has been heated to boiling. Place the mixture on a water bath and maintain at a temperature of more than 90 °C for 5 minutes, stirring repeatedly. Cover and leave to stand until cold. If gentle pressure on the drug residue does not achieve a final weight of 10 parts of mother tincture, pour a sufficient amount of boiling water over the drug residue and express gently. Use the resulting extract to make up the final weight.

Potentization
The mother tincture is equivalent to the 1st decimal dilution (ø = 1x)
The 2nd decimal dilution (2x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.

Aqueous mother tinctures made by Method 24 are normally processed immediately; they are used exclusively to produce 'Liquid dilutions for injection' by Method 11 and 'Eye drops' by Method 15, or in mixtures according to Method 16.

Aqueous mother tinctures made by Method 24 and their liquid dilutions must comply with the 'Test for sterility' of the German Pharmacopoeia if stored for further processing.

LABELLING
Preparations made by Method 24 are labelled 'Decoct.'; the same applies to

presentations made from them.

Method 24b: Heat-treated aqueous mother tinctures and liquid dilutions made from these

Aqueous other tinctures made by Method 24b are made from fresh plants or parts of plants by the method given below.

Before processing the plant material, determine loss on drying on a sample. Calculate the amount of water (W) required with the aid of the following formula:

$$W = \frac{M \cdot (400 - D)}{100} \text{ [kg]}$$

M = weight of plant material in kg

D = loss on drying in per cent

Heat the minced plant material and the calculated amount of water to a temperature of 37 °C and maintain at that temperature for 1 hour, stirring occasionally. Express and filter.

The 1st decimal dilution (1x) is made with

4 parts of the mother tincture and

6 parts of water for injections,

the 2nd decimal dilution (2x) with

1 part of the 1st decimal dilution and

9 parts of water for injections.

Subsequent dilutions are produced in the same way.

Aqueous mother tinctures made by Method 24b are normally processed immediately; they are used exclusively to produce 'Liquid dilutions for injection' by Method 11.

Aqueous mother tinctures made by Method 24b and their liquid dilutions must comply with the 'Test for sterility' of the German Pharmacopoeia if stored for further processing.

LABELLING

Preparations made by Method 24b are labelled 'Decoct.'; the same applies to presentations made from them.

Method 25: Zimpel's spagyric mother tinctures and preparations made from these

Spagyric mother tinctures made by Method 25 are produced from fresh plants or parts of plants, following the procedure given below.

Finely mince the plants or parts of plants. Using a suitable container, combine 1 part of the plant material with 1 part of water and 0.005 parts of yeast; leave to ferment at 20 - 25 °C, stirring the mixture once a day. As soon as fermentation ceases, steam distil the material into a collecting vessel containing 0.4 parts of ethanol 86 per cent per 1 part of plant material. Terminate distillation when the mixture of ethanol and distillate in the collecting vessel is two parts to one part of plant material.

Dry the expressed residue and incinerate at approx. 400 °C. Add the residue to

the distillate; filter after 48 hours.

Potentization
The 1st decimal dilution (1x) is made with
2 parts of the mother tincture and
8 parts of a mixture of 2 parts of ethanol 30 per cent and 1 part of water,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of a mixture of 2 parts of ethanol 30 per cent and 1 part of water.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 25 are labelled 'spag. Zimpel'; the same applies to presentations made from them.

Method 26: Zimpel's spagyric mother tinctures and preparations made from these Spagyric mother tinctures made by Method 26 are produced from dried plants or parts of plants, following the procedure given below.

In a suitable container, combine 1 part of the minced plant material (8,000 μm) with 3 parts of water and 0.01 parts of yeast; leave to ferment at 20 - 25 °C, stirring the mixture once a day. As soon as fermentation ceases, steam distil the material into a collecting vessel containing 2 parts of ethanol 86 per cent per 1 part of plant material. Terminate distillation when the mixture of ethanol and distillate in the collecting vessel is 10 parts to 1 part of plant material.

Dry the expressed residue and incinerate at approx. 400 °C. Add the residue to the distillate; filter after 48 hours.

Potentization
The mother tincture is equivalent to the first decimal dilution (ø = 1x).
The second decimal dilution (2x) is made with
1 part of the mother tincture and
9 parts of a mixture of 2 parts of ethanol 30 per cent and 1 part of water.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 26 are labelled 'spag. Zimpel'; the same applies to presentations made from them.

Method 27: Krauss' spagyric mother tinctures and preparations made from these Spagyric mother tinctures made by Method 27 are produced from fresh plants or parts of plants containing more than 70 per cent of moisture (loss on drying), following the procedure given below.

Finely mince the plant material and store in a cool place. Determine loss on drying on a sample. In a suitable container, combine the plant material with water, sucrose and yeast; calculate the amount of water required (W) according to the formula:

$$W = \frac{M \cdot D}{100} \text{ [kg]}$$

the amount of sucrose required (S) according to the formula:

$$S = 2 \cdot M \cdot D \text{ [g]}$$

the amount of yeast required (Y) according to the formula:

$$Y = 0.1 \cdot M \cdot D \text{ [g]}$$

M = mass of plant material in kg
D =loss on drying in sample in per cent.

Close the container with a fermentation lock and leave the mass to ferment at a temperature of approx. 35 °C. As soon as fermentation has ceased, express. Determine the ethanol concentration and adjust with ethanol 96 per cent or water to a 15 per cent (m/m) ethanol concentration. Store protected from light and at a temperature not exceeding 20 °C (extract A).

Air-dry the plant residue and percolate with ethanol 86 per cent by the method given in the German Pharmacopoeia under **Extrakte**; calculate the amount of ethanol 86 per cent required (E) according to the formula

$$E = \frac{M \cdot D}{100} \text{ [kg]}$$

M = mass of fresh plant material in kg
D = loss on drying in sample in per cent.
(Extract B).

Potentize Extract A) and Extract B) separately and produce the mother tincture and dilutions of it in the same way as for Method 27.

Potentization of Extract A)
The 1st decimal dilution (1x) is made with
2 parts of Extract A) and
8 parts of ethanol 15 per cent.

Potentization of Extract B)
The 1st decimal dilution (1x) is made with
1 part of Extract B) and
9 parts of ethanol 86 per cent,
the 2nd decimal dilution (2x) with
1 part of the 1st decimal dilution (1x) and
9 parts of ethanol 86 per cent.
The mother tincture (3x) is made with
1 part of the 2nd decimal dilution (2x) of Extract A),

1 part of the 2nd decimal dilution (2x) of Extract B) and
8 parts of ethanol 30 per cent.
Filter if required.
The 4th decimal dilution (4x) is made with
1 part of the mother tincture (3x) and
9 parts of ethanol 30 per cent.
Subsequent dilutions are produced in the same way.

LABELLING
Preparations made by Method 27 are labelled 'spag. Krauss'; the same applies to presentations made from them.

Method 28: Krauss' spagyric mother tinctures and preparations made from these Spagyric mother tinctures made by Method 28 are produced from fresh plants or parts of plants containing not less than 40 and not more than 70 per cent of moisture (loss on drying), following the procedure given with Method 27.

Unlike with Method 27, calculate the amount of water required (W) according to the formula:

$$W = \frac{2 \cdot M \cdot D}{100} \text{ [kg]}$$

the amount of sucrose required (S) according to the formula:

$$S = 3 \cdot M \cdot D \text{ [g]}$$

the amount of yeast required (Y) according to the formula:

$$Y = 0.15 \cdot M \cdot D \text{ [g]}$$

the amount of ethanol 86 per cent (E) required for percolation according to the formula in Method 27.

M = mass of fresh plant material in kg
D = loss on drying in sample in per cent.

Continue to potentize Extract A) and produce potencies of Extract B) separately to the 2nd decimal dilution (2x) and combine to produce the mother tincture (3x).

Potentization of Extract A)
The 1st decimal dilution (1x) is made with
3 parts of Extract A) and
7 parts of ethanol 15 per cent.

Potentize Extract A) and Extract B) and produce the mother tincture and dilutions of it in the same way as for Method 27.

LABELLING Preparations made by Method 28 are labelled 'spag. Krauss'; the same applies to presentations made from them.

Method 29: Krauss' spagyric mother tinctures and preparations made from these Spagyric mother tinctures made by Method 29 are produced from fresh plants or parts of plants containing not more than 40 per cent of moisture (loss on drying), following the procedure given with Method 27.

Unlike with Method 27, calculate the amount of water required (W) according to the formula:

$$W = \frac{3 \cdot M \cdot D}{100} \text{ [kg]}$$

the amount of sucrose required (S) according to the formula:

$$S = 4 \cdot M \cdot D \text{ [g]}$$

the amount of yeast required (Y) according to the formula:

$$Y = 0.2 \cdot M \cdot D \text{ [g]}$$

the amount of ethanol 86 per cent (E) required for percolation according to the following formula:

$$E = \frac{2 \cdot M \cdot D}{100} \text{ [kg]}$$

M = mass of fresh plant material in kg
D = loss on drying in sample in per cent.

Potentize Extract A) and Extract B) separately to the 2nd decimal dilution (2x) and combine to produce the mother tincture (3x).

Potentization of Extract A)
The 1st decimal dilution (1x) is made with
4 parts of Extract A) and
6 parts of ethanol 15 per cent.

Continue to potentize Extract A) and produce potencies of Extract B) and produce the mother tincture and dilutions of it in the same way as for Method 27.

Potentization of Extract B)
The 1st decimal dilution (1x) is made with
2 parts of Extract B) and
8 parts of ethanol 86 per cent,

Potentize Extract A) and Extract B) and produce the mother tincture and dilutions of it in the same way as for Method 27.

LABELLING
Preparations made by Method 29 are labelled 'spag. Krauss'; the same applies to presentations made from them.

Method 30: Krauss' spagyric mother tinctures and preparations made from these Spagyric mother tinctures made by Method 30 are produced from dried plants or parts of plants, following the procedure given with Method 27.

Unlike with Method 27, the aqueous mixture consists of 100 parts of powdered plant drug (710 µm), 400 parts of water, 40 parts of sucrose and 2 parts of yeast. The expressed plant residue is percolated with 4 parts of ethanol 86 per cent to 1 part of air-dried residue.

Extract A) and Extract B) are equivalent to the 1st decimal dilution (1x). Potentize separately to the 2nd decimal dilution (2x) and combine to produce the mother tincture (3x). Potentize Extract A) and Extract B) according to Method 27. The mother tincture (3x) is made with

0.5 parts of the 2nd decimal dilution (2x) of Extract A),
0.5 parts of the end decimal dilution (2x) of Extract B) and
9 parts of ethanol 30 per cent.

Filter if required.

Potentize the mother tincture (3x) according to Method 27.

LABELLING

Preparations made by Method 30 are labelled 'spag. Krauss'; the same applies to presentations made from them.

Method 31: Spagyric mother tinctures and preparations made from these Spagyric mother tinctures made by Method 31 are produced from fresh plants or parts of plants, following the procedure given below.

Mince the plants or parts of plants very finely. In a suitable container, combine 100 parts of plant material with 200 parts of water and 0.05 parts of yeast. Leave to ferment at a temperature of 18 °C, stirring the mixture daily. As soon as fermentation has ceased, adjust to an ethanol content of between 10.0 and 15.0 per cent, using ethanol 86 per cent; the ethanol resulting from fermentation is taken into account.

Distil at a pressure of 3.2 bar, using suitable apparatus. Dry the residue and incinerate at a temperature above 700 °C; let the ash cool down to approx. 150 °C and combine with the distillate.

Distil the resulting mixture at normal pressure. Dry the residue and incinerate at a temperature above 850 °C. Let the ash cool and combine with the distillate. 24 hours after adding the ash stir the mixture thoroughly; filter after another 60 hours. The filtrate represents the mother tincture.

Potentization

The first decimal dilution (1x) is made with

1 part of the mother tincture and
9 parts of a mixture of 1 part of ethanol 86 per cent and 4 parts of isotonic saline.

Subsequent dilutions are produced in the same way.

LABELLING

Preparations made by Method 31 are labelled 'spag. bidest.'; the same applies to presentations made from them.

Method 32: Buffered aqueous mother tinctures and liquid dilutions made from them

Buffered aqueous mother tinctures made by Method 32 are produced by macerating fresh plants or parts of plants, using the procedure given below.

Before the material is processed, take a sample and determine loss on drying. To 1 part of the plant material add 2 parts of ascorbate phosphate buffer solution and reduce the mixture to a homogenous slurry.

Calculate the total amount of ascorbate phosphate buffer solution (B) required according to the following formula, subtract the amount already used and add the remainder to the mixture.

$$B = \frac{4 \cdot M \cdot D}{100} \text{ [kg]} \qquad (3)$$

M = weight of the plant material in kg
D = loss on drying in the sample in per cent
Express and filter after not more than 60 minutes.

Potentization

The first decimal dilution (1x) is made with
1 part of the mother tincture and
1 part of ascorbate phosphate buffer solution,
the second decimal dilution (2x) with
1 part of the 1st decimal dilution and
9 parts of ascorbate phosphate buffer solution.

Subsequent dilutions are produced by the same method. Up to and including the 5th decimal dilution potentize with ascorbate phosphate buffer solution, from the 6th decimal solution onwards with isotonic saline.

With mother tinctures and liquid dilutions with high frothing potential potentization differs from the usual method; in containers filled so that there are no bubbles, potentize by mixing for not less than 1 minute in a device that produces rotary, tipping or rocking movements in constantly alternating acceleration and deceleration.

Buffered aqueous mother tinctures made by Method 32 are processed immediately. They are exclusively intended for the manufacture of 'Liquid dilutions for injection' by Method 11.

Liquid dilutions prepared by Method 32 must comply with the 'Test for Sterility' of the German Pharmacopoeia if stored for further processing.

LABELLING

Preparations made by Method 32 are labelled 'col.'; the same applies to presentations made from them.

Method 33a: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them

Aqueous mother tinctures made by Method 33a are produced by macerating and

fermenting fresh plants or parts of plants, using the procedure given below.

Combine 100 parts of finely minced plant material with 0.75 parts of honey, 0.75 parts of lactose and 50 parts of water; determine the pH of the mixture. Every morning and evening place the mixture for a two-hour period in a mixture of ice and water; stir well before and after this. At all other times maintain on a water bath at approx. 37 °C. As soon as the pH begins to drop, maintain the mixture at room temperature, except for the two two-hour cooling periods per day. Unless otherwise stated in the Monograph, express after 3 1/2 days during one of the cooling phases. Continue to place the expressed liquid in a mixture of ice and water every morning and evening for 3 1/2 days; stir well immediately before and after doing so. For the rest of the time keep at room temperature. After 3 1/2 days filter the liquid through muslin; the filtrate is naturally cloudy.

Incinerate an adequate amount of the air-dried expressed plant residue in a porcelain crucible at a temperature where it turns a dark red. Immediately after filtration, add approx. 50 mg of ash per 100 ml of the filtrate. This mixture represents the mother tincture.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with

1 part of the mother tincture and

9 parts of a mixture of 1 part of ethanol 86 per cent and 4 parts of isotonic saline.

Subsequent dilutions are produced in the same way.

The first centesimal dilution (1c) is made with

1 part of the mother tincture and

99 parts of water for injections.

Liquid dilutions made by Method 33a must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING

Preparations made by Method 33a are labelled 'ferm 33a'; the same applies to presentations made from them.

STORAGE

Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 33b: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them

Aqueous mother tinctures made by Method 33b are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given under Method 33a.

Method 33b differs from Method 33a in that the mixture is made up with 100 parts of finely minced plant material, 0.75 parts of honey, 0.75 parts of lactose and 75 parts of water.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization
The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.
The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.
Liquid dilutions made by Method 33b must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING
Preparations made by Method 33b are labelled 'ferm 33b'; the same applies to presentations made from them.

STORAGE
Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 33c: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them
Aqueous mother tinctures made by Method 33c are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given under Method 33a.
Method 33c differs from Method 33a in that the mixture is made up with 100 parts of finely minced plant material, 0.75 parts of honey, 0.75 parts of lactose and 125 parts of water.
Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization
The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.
The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.
Liquid dilutions made by Method 33c must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING
Preparations made by Method 33c are labelled 'ferm 33c'; the same applies to presentations made from them.

STORAGE
Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 33d: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them

Aqueous mother tinctures made by Method 33d are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given under Method 33a.

Method 33d differs from Method 33a in that the mixture is made up with 100 parts of finely minced plant material, 0.75 parts of honey, 0.75 parts of lactose and 200 parts of water.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.

The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.

The first vicesimal dilution (H) is made with
1 part of the mother tincture and
19 parts of water for injections.

Subsequent dilutions are produced in the same way. They are designated as follows: 2nd dilution as G, 3rd dilution as F, 4th dilution as E, 5th dilution as D, 6th dilution as C, 8th dilution as B and 10th dilution as A.

Liquid dilutions made by Method 33d must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING
Preparations made by Method 33d are labelled 'ferm 33d'; the same applies to presentations made from them.

STORAGE
Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 33e: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them

Aqueous mother tinctures made by Method 33e are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given under Method 33a.

Method 33e differs from Method 33a in that the mixture is made up with 100 parts of finely minced plant material, 0.75 parts of honey, 0.75 parts of lactose and 275 parts of water.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization
The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.
The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.
Liquid dilutions made by Method 33e must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING
Preparations made by Method 33e are labelled 'ferm 33e'; the same applies to presentations made from them.

STORAGE
Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 34a: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them
Aqueous mother tinctures made by Method 34a are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given under Method 33a.
Method 34a differs from Method 33a in that the mixture is made up with 100 parts of finely minced plant material and 50 parts of whey.
Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization
The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.
The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.
Liquid dilutions made by Method 34a must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING
Preparations made by Method 34a are labelled 'ferm 34a'; the same applies to presentations made from them.

STORAGE
Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 34b: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them

Aqueous mother tinctures made by Method 34b are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given under Method 33a.

Method 34b differs from Method 33a in that the mixture is made up with 100 parts of finely minced plant material, 25 parts of water and 50 parts of whey.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.

The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.

Liquid dilutions made by Method 34b must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING
Preparations made by Method 34b are labelled 'ferm 34b'; the same applies to presentations made from them.

STORAGE
Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 34c: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them

Aqueous mother tinctures made by Method 34c are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given under Method 33a.

Method 34c differs from Method 33a in that the mixture is made up with 100 parts of finely minced plant material, 75 parts of water and 50 parts of whey.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.

The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.
Liquid dilutions made by Method 34c must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING
Preparations made by Method 34c are labelled 'ferm 34c'; the same applies to presentations made from them.

STORAGE
Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 34d: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them
Aqueous mother tinctures made by Method 34d are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given under Method 33a.
Method 34d differs from Method 33a in that the mixture is made up with 100 parts of finely minced plant material, 110 parts of water and 15 parts of whey.
Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization
The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.
The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.
Liquid dilutions made by Method 34d must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING
Preparations made by Method 34d are labelled 'ferm 34d'; the same applies to presentations made from them.

STORAGE
Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 34e: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them
Aqueous mother tinctures made by Method 34e are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given under

Method 33a.

Method 34e differs from Method 33a in that the mixture is made up with 100 parts of finely minced plant material, 225 parts of water and 50 parts of whey.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with

1 part of the mother tincture and

9 parts of water for injections.

Subsequent dilutions are produced in the same way.

The first centesimal dilution (1c) is made with

1 part of the mother tincture and

99 parts of water for injections.

Subsequent dilutions are produced in the same way.

Liquid dilutions made by Method 34e must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING

Preparations made by Method 34e are labelled 'ferm 34e'; the same applies to presentations made from them.

STORAGE

Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 35a: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them

Aqueous mother tinctures made by Method 35a are produced by macerating and fermenting fresh plants or parts of plants, using the procedure given below.

Divide 100 parts of finely minced plant material into 7 portions. In the morning, combine 1 portion of the finely minced plant material with 0.75 parts of honey and 500 parts of water; determine the pH of the mixture. Place the mixture in a water bath at about 37 °C. In the evening, place the mixture for a two-hour period In a mixture of ice and water; stir well immediately before and after this. Return the mixture to the water bath at approx. 37 °C. Express the mixture 24 hours after first preparing it and determine the pH of the liquid.

Add another portion of the finely minced plant material to the extract and in the evening place for 2 hours in a mixture of ice and water; stir immediately before and after this. If the pH has not changed, keep the mixture of a water bath at about 37 °C for the remaining time; if the pH has decreased, keep the mixture at room temperature. Express 24 hours after first making the mixture and determine the pH of the liquid.

Proceed in the same way with the 5 remaining portions of plant material over the next 5 days. Leave the final liquid to stand for some hours before filtering through muslin; the filtrate is naturally turbid.

Incinerate an adequate amount of the air-dried expressed plant residue in a porcelain crucible at a temperature where it turns a dark red. Immediately after

filtration, add approx. 50 mg of ash per 100 ml of the filtrate. This mixture represents the mother tincture.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with

1 part of the mother tincture and

9 parts of water for injections.

Prepare subsequent dilutions in the same way.

The first decimal dilution (1c) is made with

1 part of the mother tincture and

99 parts of water for injections.

Prepare subsequent dilutions in the same way.

Liquid dilutions made by Method 35a must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING

Preparations made by Method 35a are labelled 'ferm 35a'; the same applies to presentations made from them.

STORAGE

Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 35b: Heat-treated and fermented aqueous mother tinctures and liquid dilutions made from them.

Aqueous mother tinctures made by Method 35b are produced by macerating and fermenting dried plants, parts of plants or plant secretions, using the procedure given under Method 35a.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with

1 part of the mother tincture and

9 parts of water for injections.

Subsequent dilutions are produced in the same way.

The first centesimal dilution (1c) is made with

1 part of the mother tincture and

99 parts of water for injections.

Subsequent dilutions are produced in the same way.

Liquid dilutions made by Method 35b must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before processing.

LABELLING

Preparations made by Method 35b are labelled 'ferm 35b'; the same applies to presentations made from them.

STORAGE
Protected from light, in tightly sealed containers; the mother tincture below 15 °C.

Method 36: Heat-treated and fermented aqueous mother tinctures and liquid dilutions of these

Aqueous mother tinctures made by Method 36 are produced by macerating and fermenting dried plants or parts of plants or plant secretions, following the procedure given under Method 35a.

Method 36 differs from Method 35a in that the first mixture is made with the finely minced first portion of plant material, 300 parts of water and 200 parts of whey.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.

The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.

Subsequent dilutions are produced in the same way.

Liquid dilutions made by Method 36 must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before further processing.

LABELLING
Preparations made by Method 36 are labelled 'ferm 36'; the same applies to presentations made from them.

STORAGE
Protected from light, in well sealed containers; the mother tincture at below 15 °C.

Method 37a: Heat-treated and fermented aqueous mother tinctures and liquid dilutions of these

Aqueous mother tinctures made by Method 37a are produced by macerating and fermenting fresh plants or parts of plants, following the procedure given below.

Divide 100 parts of the plant material into 7 portions. The first mixture is made up in the morning, using one portion of the finely minced plant material, 0.15 parts of finely powdered haematite and 50 parts of water. Place the mixture on a water bath at approx. 37 °C. In the evening, place the mixture for 2 hours in a mixture of ice and water, stirring well before and after the 2-hour period. Replace on the water bath at approx. 37 °C. Express 24 hours after making up the mixture.

The next mixture is made up with the expressed liquid, another portion of finely minced plant material and 0.15 parts of finely powdered haematite and treated like the first mixture. Process the remaining 5 portions in the same way during the 5 days that follow. Leave the final expressed liquid to stand for a few

hours before filtering through muslin. The filtrate is naturally cloudy.

Incinerate an adequate amount of the air-dried plant residue in a porcelain crucible at a temperature where it turns a dark red. Immediately after filtration, add approx. 50 mg of ash per 100 ml of the filtrate. This mixture represents the mother tincture.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.

The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.

Liquid dilutions made by Method 37a must comply with the 'Test for sterility' in the German Pharmacopoeia if stored before further processing.

LABELLING

Preparations made by Method 37a are labelled 'ferm cum ferro'; the same applies to presentations made from them.

STORAGE

Protected from light, in well sealed containers; the mother tincture at below 15 °C.

Method 37b: Heat-treated and fermented aqueous mother tinctures and liquid dilutions of these

Aqueous mother tinctures made by Method 37b are produced by macerating and fermenting fresh plants or parts of plants, following the procedure given under Method 37a.

Method 37b differs from Method 37a in that the finely powdered haematite is replaced with the same amount of finely powdered zinc.

Wait not less than 6 months after adding the ash before processing the mother tincture. Discard any sediment that may have formed.

Potentization

The first decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of water for injections.
Subsequent dilutions are produced in the same way.

The first centesimal dilution (1c) is made with
1 part of the mother tincture and
99 parts of water for injections.
Subsequent dilutions are produced in the same way.

Liquid dilutions made by Method 37b must comply with the 'Test for sterility'

in the German Pharmacopoeia if stored before further processing.

LABELLING
Preparations made by Method 37b are labelled 'ferm cum zinco'; the same applies to presentations made from them.

STORAGE
Protected from light, in well sealed containers; the mother tincture at below 15 °C.

Method 38: Cold-treated aqueous mother tinctures and liquid dilutions made from them
Aqueous mother tinctures made by Method 38 are produced by macerating dried plants or parts of plants in the cold ('C'), following the procedure given below.

Combine the finely minced plant material with six times the amount (w/w) of a solution made with 8.8 parts of sodium chloride, 0.2 parts of sodium hydrogen carbonate and 991 parts of water. Store the mixture at a temperature of approx. 4 °C for 14 days, stirring well every morning and evening. Express. Store the expressed liquid at a temperature of approx. 4 °C and protected from light until the supernatant liquid is completely clear. The clear supernatant liquid represents the mother tincture. Process completely and immediately.

Potentization
The 1st vicesimal dilution (H) is made with
1 part of the mother tincture and
19 parts of water for injections.

Subsequent dilutions are produced in the same way and labelled as follows: 2nd dilution as G, 3rd dilution as F, 4th dilution as E, 5th dilution as D, 6th dilution as C, 8th dilution as B and 10th dilution as A.

Mother tinctures made by Method 38 are processed immediately. They are used exclusively for the manufacture of 'Liquid dilutions for injection' made by Method 11.

LABELLING
Preparations made by Method 38 are labelled 'C' ('K' in German); the same applies to presentations made from them.

Method 39a: Globuli velati (coated granules)
Preparations made by Method 39a are coated granules produced by the even application of a liquid preparation to size 5 sucrose granules (40-50 granules weigh 1 g).

To produce 100 parts of coated granules, combine 1 part of a preparation made by Methods 33-37 with 9 parts of sugar syrup and potentize by succussion; evenly apply these 10 parts to 100 minus x parts of sucrose granules, where x is the amount of sucrose in the sugar syrup.

LABELLING
Coated granules made by Method 39a are labelled to indicate the dilution stage of

the applied preparation.

Method 39b: Globuli velati (coated granules)
Preparations made by Method 39b are coated granules produced by the even application of a solid preparation to size 5 sucrose granules (40-50 granules weigh 1 g).

To produce 100 parts of coated granules, combine 1 part of a mixture of 10 parts of a trituration made by Method 6 and 20 parts of sugar syrup and apply evenly to 100 minus x minus y parts of sucrose granules, where x is the amount of sucrose in the sugar syrup and y is the amount of lactose in the incorporated trituration.

LABELLING
Coated granules made by Method 39b are labelled to indicate the dilution stage of the applied trituration.

Method 39c: Globuli velati (coated granules)
Preparations made by Method 39c are coated granules produced by the even application of a mixture made by Method 16, No. 3, to size 5 sucrose granules (40-50 granules weigh 1 g).

The mixture to be applied is produced with preparations made by Methods 6, 23, 24, 33a-e, 34-a-e, 35a-b, 36, 37a-b, 40b, and 40c and an adequate amount of sugar syrup. To produce 100 parts of Globuli velati, apply the mixture evenly to 100 minus x minus y parts of sucrose granules, where x is the amount of sucrose in the sugar syrup and y is the amount of lactose in the incorporated triturations.

LABELLING
Indicate the composition so that the type and amount of incorporated liquid and/or solid preparations are clearly apparent.

Method 40a: Potentized mixtures
Mixtures potentized by Method 40a may contain basic drug materials, solutions or triturations in combination with liquid preparations, liquid dilutions, and/mother tinctures which according to the Method of preparation are to be processed in a 1 : 10 ratio. Method 40a is limited to potentization of combined liquid preparations produced by Methods using a mixture of ethanol and water as the vehicle.

Potentization
Combine and succuss 1 part of the given mixture and 9 parts of ethanol in a suitable concentration for each potentizing stage.

Potentized mixtures may be used to produce all types of presentation. For 'Liquid dilutions for injection' made by Method 11 and 'Eye drops' made by Method 15, use the vehicle given in the Method for the final potentizing stage.

LABELLING
State the number of potentizing stages applied to the mixture; the same applies to presentations produced from potentized mixtures.

Method 40b: Potentized mixtures

Mixtures potentized by Method 40b may contain liquid preparations made by Methods 5b, 8b, 23, 24, 33a-e, 34a-e, 35a-b, 36, 37a-b, 41a-c and triturations made by Method 6.

Potentization

Combine and succuss 1 part of the given mixture and 9 parts of the vehicle for each potentizing stage. If the mixture contains preparations made by Methods 41a-c, use the vehicle given under those Methods for potentization. If mixtures potentized by Method 40b are used to produce Globuli velati, use sugar syrup as the vehicle for the final potentization stage; in all other cases use water for injections as the vehicle.

Mixtures potentized by Method 40b must comply with the 'Sterility test' in the German Pharmacopoeia if stored.

Potentized mixtures may be used to produce all types of presentation. For 'Liquid dilutions for injection' made by Method 11 and 'Eye drops' made by Method 15, use the vehicle given in the Method for the final potentizing stage.

LABELLING

State the number of potentizing stages applied to the mixture; the same applies to presentations produced from potentized mixtures.

Method 40c: Potentized mixtures

Mixtures potentized by Method 40c contain triturations made by Methods 6 and/or 7.

Potentization

Combine and triturate 1 part of the mixture and 9 parts of lactose for each potentizing stage, following the procedure given under Method 6.

Potentized mixtures may be used to produce all types of presentation.

LABELLING

State the number of potentizing stages applied to the mixture; the same applies to presentations produced from potentized mixtures.

Method 41a: Gl mother tinctures and liquid dilutions made from these

Gl mother tinctures made by Method 41a are produced by macerating animals, parts of animals or animal secretions with a glycerol solution (Gl) containing sodium chloride, following the procedure given below. Higher (warm-blooded) animals are processed immediately after slaughter. Lower animals are killed immediately before they are processed by gassing with CARBON DIOXIDE in a covered vessel.

Combine 1 part of finely minced animal material with 5 parts of a 1.5 per cent solution (w/w) of sodium chloride; after this add 95 parts of GLYCEROL. Store protected from light for not less than 7 days. Decant and if necessary filter through muslin. Bring any sediment present into suspension before processing the Gl mother tincture.

Potentization

The vehicle used for potentization is a solution of 0.2 part of sodium hydrogen carbonate and 8.8 parts of sodium chloride in 91 parts of WATER FOR INJECTIONS.

The Gl mother tincture is equivalent to the 2nd decimal dilution (ø = 2x) and the 1st centesimal dilution (ø = 1c).

The third decimal dilution (3x) is made with
1 part of the Gl mother tincture and
9 parts of the above vehicle.

Subsequent dilutions are produced in the same way.

The second centesimal dilution (2c) is made with
1 part of the Gl mother tincture and
99 parts of the above vehicle.

Subsequent dilutions are produced in the same way.

Gl mother tinctures made by Method 41a are used exclusively for the manufacture of preparations by Methods 7, 11, 13, 14, 15 and 39a-c, in mixtures made by Method 16, and in potentized mixtures made by Method 40b.

Liquid dilutions made by Method 41a must comply with the 'Test for sterility' in the German Pharmacopoeia if stored before processing.

LABELLING

Preparations made by Method 41a are labelled 'Gl'; the same applies to presentations made from them.

Method 41b: Gl mother tinctures and liquid dilutions made from these

Gl mother tinctures made by Method 41b are produced by macerating animals, parts of animals or animal secretions with a glycerol solution (Gl) containing sodium chloride, following the procedure given below. Higher (warm-blooded) animals are processed immediately after slaughter. Lower animals are killed immediately before they are processed by gassing with CARBON DIOXIDE in a covered vessel.

Combine 1 part of finely minced animal material with 5 parts of a 4 per cent solution (w/w) of sodium chloride; after this add 95 parts of GLYCEROL. Store protected from light for not less than 7 days. Decant and if necessary filter through muslin. Bring any sediment present into suspension before processing the Gl mother tincture.

Potentization

The vehicle used for potentization is a solution of 0.2 part of sodium hydrogen carbonate and 8.8 parts of sodium chloride in 91 parts of WATER FOR INJECTIONS.

The Gl mother tincture is equivalent to the 2nd decimal dilution (ø = 2x) and the 1st centesimal dilution (ø = 1c).

The third decimal dilution (3x) is made with
1 part of the Gl mother tincture and
9 parts of the above vehicle.

Subsequent dilutions are produced in the same way.

The second centesimal dilution (2c) is made with
1 part of the Gl mother tincture and

99 parts of the above vehicle.

Subsequent dilutions are produced in the same way.

Gl mother tinctures made by Method 41b are used exclusively for the manufacture of preparations by Methods 7, 11, 13, 14, 15 and 39a-c, in mixtures made by Method 16, and in potentized mixtures made by Method 40b.

Liquid dilutions made by Method 41b must comply with the 'Test for sterility' in the German Pharmacopoeia if stored before processing.

LABELLING

Preparations made by Method 41b are labelled 'Gl'; the same applies to presentations made from them.

Method 41c: Gl mother tinctures and liquid dilutions made from these

Gl mother tinctures made by Method 41c are produced by macerating animals, parts of animals or animal secretions with a glycerol solution (Gl) containing sodium chloride, following the procedure given below. Higher (warm-blooded) animals are processed immediately after slaughter. Lower animals are killed immediately before they are processed by gassing with CARBON DIOXIDE in a covered vessel.

Combine 1 part of finely minced animal material with 5 parts of an 8 per cent solution (w/w) of sodium chloride; after this add 95 parts of GLYCEROL. Store protected from light for not less than 7 days. Decant and if necessary filter through muslin. Bring any sediment present into suspension before processing the Gl mother tincture.

Potentization

The vehicle used for potentization is a solution of 0.2 part of sodium hydrogen carbonate and 8.8 parts of sodium chloride in 91 parts of WATER FOR INJECTIONS.

The Gl mother tincture is equivalent to the 2nd decimal dilution (ø = 2x) and the 1st centesimal dilution (ø = 1c).

The third decimal dilution (3x) is made with

1 part of the Gl mother tincture and

9 parts of the above vehicle.

Subsequent dilutions are produced in the same way.

The second centesimal dilution (2c) is made with

1 part of the Gl mother tincture and

99 parts of the above vehicle.

Subsequent dilutions are produced in the same way.

Gl mother tinctures made by Method 41c are used exclusively for the manufacture of preparations by Methods 7, 11, 13, 14, 15 and 39a-c, in mixtures made by Method 16, and in potentized mixtures made by Method 40b.

Liquid dilutions made by Method 41c must comply with the 'Test for sterility' in the German Pharmacopoeia if stored before processing.

LABELLING

Preparations made by Method 41c are labelled 'Gl'; the same applies to presentations made from them.

Method 42: Mother tinctures and liquid dilutions
Mother tinctures made by Method 42 are made from freshly slaughtered animals or parts of these and a liquid vehicle. Disperse 1 part of finely minced animal material in 9 parts (= 1x) or 99 parts (= 1c or 2x) of glycerol 85 per cent and succuss. Filter if required.

Potentization
The 2nd decimal dilution (2x) is made with
1 part of the mother tincture (1x) and
9 parts of glycerol 85 per cent,
the 3rd decimal dilution (3x) with
1 part of the 2nd decimal dilution or 1 part of the mother tincture (2x) and
9 parts of ethanol 15 per cent.
Subsequent dilutions are made in the same way.
The 2nd centesimal dilution (2c) is made with
1 part of the mother tincture (1c) and
99 parts of ethanol 15 per cent.
Subsequent dilutions are made in the same way.

Method 43: Mother tinctures and liquid dilutions
Mother tinctures made by Method 43 are made from animal or human organs or parts of organs that are subject to pathological changes. Disperse 1 part of minced starting material, which must comply with the 'Test for sterility' in the German Pharmacopoeia, in 10 parts of glycerol 85 per cent. Leave to stand for not less than 5 days before filtering.

Potentization
The mother tincture is equivalent to the 1st decimal dilution (ø = 1x).
The 2nd decimal dilution (2x) is made with
1 part of the mother tincture and
9 parts of ethanol 30 per cent,
the 3rd decimal dilution (3x) with
1 part of the 2nd decimal dilution and
9 parts of ethanol 43 per cent, unless another liquid vehicle is prescribed.
Subsequent dilutions are made in the same way.
The first centesimal dilution (1c) is made with
10 parts of the mother tincture and
90 parts of ethanol 30 per cent,
the 2nd centesimal dilution (2c) with
1 part of the 1st centesimal dilution (1c) and
99 parts of ethanol 43 per cent, unless another liquid vehicle is prescribed.
Subsequent dilutions are made in the same way.

Method 44: Mother tinctures and liquid dilutions
Mother tinctures made by Method 44 are made from killed cultures of microorganisms or from decomposition products of animal organs or from body fluids containing pathogens or pathological products. Combine and succuss 1 part

of the starting material—this must comply with the 'Test for sterility' in the German Pharmacopoeia—with 9 parts of glycerol 85 per cent. Leave to stand for not less than 5 days, then filter if required.

Unless otherwise stated in the Monograph, adjust cultures to 10^7 microorganisms per gram before sterilizing them.

Potentization

The mother tincture is equivalent to the 1st decimal dilution (ø = 1x).
The 2nd decimal dilution (2x) is made with
1 part of the mother tincture and
9 parts of ethanol 30 per cent,
the 3rd decimal dilution (3x) with
1 part of the 2nd decimal dilution and
9 parts of ethanol 43 per cent, unless another liquid vehicle is prescribed.
Subsequent dilutions are made in the same way.
The first centesimal dilution (1c) is made with
10 parts of the mother tincture and
90 parts of ethanol 30 per cent,
the 2nd centesimal dilution (2c) with
1 part of the 1st centesimal dilution (1c) and
99 parts of ethanol 43 per cent, unless another liquid vehicle is prescribed.
Subsequent dilutions are made in the same way.

Method 45: Nasal drops

Preparations made by Method 45 are aqueous liquids with a residual ethanol concentration of not more than one per cent.

They are made with one or more homoeopathic preparations and comply with the requirements of the **Nasentropfen** monograph in the German Pharmacopoeia.

Apart from auxiliaries used to preserve, increase viscosity, isotonize and adjust pH, no additives are permitted.

Potentize the last two decimal dilutions and the last centesimal dilution respectively with water for injections or the solution of isotonizing agent, usually sodium chloride; other isotonizing agents must be declared. Ethanol-free vehicles may also be added.

STORAGE

Protected from light.

LABELLING

Potency stages potentized to a higher level together must be stated, as must be the addition of drug vehicles.

Method 46: Liquid vinous dilutions

Preparations made by Method 46 are liquid decimal dilutions produced by potentizing liquid dilutions made by Methods 1, 2a, 3a, 4a, 5a or 8a through two potentizing stages with liqueur wine. Liquid dilutions made by Methods 1, 2a, 3a and 5a can only be potentized with liqueur wine from the 2nd decimal dilution (2x)

onwards; on the other hand all dilutions made by Method 8, including the 6x and 7x, may be potentized through two stages with liqueur wine using Method 46.

Liquid vinous dilutions made by Method 46 are processed immediately; they are intended exclusively for the manufacture of mixtures by Method 16.

LABELLING
Preparations made by Method 46 are labelled 'vinos'.

Method 47a: Pekana's spagyric mother tinctures and liquid dilutions of these Spagyric mother tinctures made by Method 47a are produced from fresh plants or parts of plants using the method given below.

Finely mince the plants or parts of plants. In a suitable container combine 1 part of plant material, 6 parts of water, 1 part of sucrose and 0.005 parts of yeast. Close the container with a fermentation lock and leave the mass to ferment at a temperature of approx. 20 - 25 °C. As soon as fermentation has ceased, decant the liquid part and express the plant residue. Adjust with ethanol 86 per cent or water to a 15 per cent ethanol concentration. Dry the plant residue and incinerate at about 900 °C. When the ash has cooled to about 20 °C, dissolve it in part of the ethanolic fraction and add to the total liquid. Filter after about 48 hours. This mixture is the mother tincture.

Potentization
The 1st decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of ethanol 15 per cent.
Subsequent dilutions are made in the same way.

LABELLING
Preparations made by Method 47a are labelled 'spag. Peka'; the same applies to presentations made from them.

Method 47b: Pekana's spagyric mother tinctures and liquid dilutions of these Spagyric mother tinctures made by Method 47b are produced from fresh plants or parts of plants using the method given as Method 47a.

Method 47b differs from Method 47a in that the powdered drug (710 µm) is mixed in cold water in a ratio of 1 : 6 and left to stand for 1 day. In a suitable container combine 1 part of the mixture with 1 part of sucrose and 0.005 parts of yeast. Ferment at a temperature of approx. 20 - 25 °C.

Potentization
The 1st decimal dilution (1x) is made with
1 part of the mother tincture and
9 parts of ethanol 15 per cent.
Subsequent dilutions are made in the same way.

LABELLING
Preparations made by Method 47b are labelled 'spag. Peka'; the same applies to

presentations made from them.

Method 48: Ointments containing powdered metal
Ointments containing powdered metal produced by Method 48 contain powdered metal in an ointment base. They are exclusively produced for the manufacture of ointments by Method 13. Manufacture by mixing 1 part of the metal powder into 9 parts of ointment base. 80 per cent of the metal particles are less than 10 μm in diameter; no particle is larger than 50 μm.

Presentations made by Method 48 must comply with the Salben monograph in the German Pharmacopoeia.

LABELLING
Ointments containing powdered metal produced by Method 48 are labelled 'M'.

Method 49: Aqueous mother tinctures and liquid dilutions of these
Aqueous mother tinctures produced by Method 49 are made by macerating fresh plants or parts of plants by the following method.

Determine loss on drying and add the amount of water calculated as under Method 23b to the minced plant material. Express the plant material after not more than 2 hours and filter.

Potentize as for Method 23b.

Aqueous mother tinctures made by Method 49 are normally processed immediately. They are exclusively used to produce presentations by Method 11 and Method 15.

Aqueous mother tinctures made by Method 49 must comply with the 'Test for sterility' of the German Pharmacopoeia if stored before further processing.

LABELLING
Preparations made by Method 49 are labelled 'aquos'; the same applies to presentations made from them.

Method 50a: Strathmeyer's spagyric mother tinctures and liquid dilutions of these
Spagyric mother tinctures produced by Method 50a are made with dried plants or parts of plants or mixtures of dried plants or parts of plants and Strath yeast (*Candida utilis* cultivated with the drug extract specified in Methods 50a and 50b) by the method given below.

Put 5 parts of the minced drug in a suitable container and add 75 parts of water, 19 parts of sucrose and 1 part of yeast. Leave to ferment at 24 - 29 °C. After 3 days add 1 more part of yeast and leave to ferment for 3 more days. Express and process the drug extract immediately.

In a separate production process, macerate 25 parts of Strath yeast in 20 parts of ethanol for 5 days. Filter the yeast extract.

Combine 15 parts of yeast extract and 85 parts of drug extract and filter. To every 100 ml of the filtrate add 50 mg of ascorbic acid. This mixture is the mother tincture.

Potentization
Combine 2 parts of the mother tincture and 8 parts of ethanol 15 per cent and potentize. This yields the 2nd decimal dilution (2x).
The 3rd decimal dilution (3x) is made with
1 part of the 2nd decimal dilution and
9 parts of ethanol 15 per cent.
Subsequent dilutions are made in the same way.

LABELLING
Preparations made by Method 50a are labelled 'spag. Strathmeyer'; the same applies to presentations made from them.

Method 50b: Strathmeyer's spagyric mother tinctures and liquid dilutions of these for the manufacture of Strathmeyer ointments
Spagyric mother tinctures produced by Method 50b are made with dried plants or parts of plants or mixtures of dried plants or parts of plants and Strath yeast (Candida utilis cultivated with the drug extract specified in Methods 50a and 50b) by the method given below.

Put 8 parts of the minced drug in a suitable container and add 74 parts of water, 14 parts of sucrose and 1 part of yeast. Leave to ferment at 24 - 29 °C for 6 days, express and filter. Store the drug extract at not more than 8 °C and protected from light for up to 6 weeks.

In a separate production process, macerate 25 parts of Strath yeast in 20 parts of ethanol for 5 days. Filter the yeast extract and evaporate to one tenth of the original mass under vacuum at a temperature not exceeding 40 °C.

Combine 1 parts of the concentrate and 99 parts of the drug extract. This mixture is the mother tincture.
Potentization
The mother tincture is equivalent to the 1st decimal dilution (ø = 1x).
The 2nd decimal dilution (2x) is made with
1 part of the mother tincture and
9 parts of ethanol 15 per cent.
Subsequent dilutions are made in the same way.

LABELLING
Preparations made by Method 50b are labelled 'spag. Strathmeyer'; the same applies to presentations made from them.

Method 50c: Strathmeyer ointments
Ointments produced by Method 50c are made from preparations produced by Method 50b and a base in a ratio of 1 : 3. The base consists of 4 parts of wool alcohols ointment and 1 part of lanolin.

The ointments comply with the **Salben** monograph of the German Pharmacopoeia.

Additives such as antioxidants, stabilizers and preservatives are not permitted.

Abies alba spag. Zimpel

Tips of non-woody fresh young twigs, with leaves and immature cones, of *Abies alba* Mill.

DESCRIPTION

The tips of twigs and cones have a resinous balsamic odour and slightly bitter, aromatic, resinous taste.

The young twigs are greyish or yellowy brown, not grooved, with fine or rough hairs but no glandular hairs. The stiff evergreen solitary leaves are spirally inserted on the stem but usually twisted at the base so that they form two lateral sets. Occasionally some of the leaves are obliquely erect on either side of the central line on the stem, creating a V-shaped channel. On vertical shoots, the flat leaves, 17 - 30 mm long and 2 - 3 mm wide, grow in all directions. The upper surface is grooved, dark shining green, with normally only a few short white lines at the tip. The underside is matt, with striking whitish or bluish white waxy bands on either side of the keel-like central vein. The tip of the leaf is blunt or emarginate, the margin flat. At the base the lamina narrows down to a short green petiole that is oval in cross section and attached to the shoot by a disc-like base. On removal of the leaf the disc comes away with the petiole, leaving a flat circular scar. Buds, which may be present at the tips of twigs, are not resinous, so that the scales are clearly visible. The buds of terminal shoots are occasionally slightly resinous at the base.

The erect green, bluish green or browny green cones are cylindrical, narrowing slightly towards the rounded tip. The central axis is covered with numerous densely imbricate bracts arranged in a spiral, with ovuliferous scales in their axils. The exserted bracts are linear and spatulate, dentate and with a long pointed process at the tip. They are narrower but longer than the ovuliferous scales. The part that forms the outside of the cone stands away horizontally or is reflexed. The ovuliferous scales have a cuneate base and are broadly rounded at the top; dorsum and margins are tomentose. Two unripe seeds with truncated cuneate wings sit near the base on the upper side.

PREPARATIONS

MANUFACTURE
The mother tincture and liquid dilutions by Method 25.

CHARACTERISTICS
The mother tincture is a pale yellow liquid with aromatic odour and taste.

IDENTIFICATION
Chromatography. Use thin-layer chromatography in a ready-made silica gel H *R* plate.

Test solution: To 10 ml of the mother tincture add 10 ml of saturated sodium chloride solution *RN* and extract three times, each time with 10 ml of pentane *R*. Dry the combined organic phases over anhydrous sodium sulphate *R*, filter and evaporate to about 0.5 ml on a water bath at about 30 °C.

Dissolve the residue in 1 ml of methanol *R*.

Control solution: Dissolve 5 mg each of borneol *R* and thymol *R* in 10 ml of methanol *R*.

Apply separately 10 µl of the test solution and 10 µl of the control solution. The mobile phase is a mixture of 7 parts by volume of ethyl acetate *R* and 93 parts by volume of toluene *R*. Allow the solvent front to rise 15 cm above the line of application. Following evaporation of the solvent spray the chromatograms with anisaldehyde reagent *R*, heat to 105 - 110 °C for 10 minutes and examine in daylight.

The chromatogram of the control solution has the yellowy green borneol zone in the lower and the red thymol zone in the middle third.

The chromatogram of the test solution has a reddish violet zone at the level of the borneol standard and several mauve and reddish violet zones between the borneol standard and the line of application; immediately above the borneol standard are a faintly mauve and a red zone, below the thymol standard a reddish violet and below the solvent front a bluish violet zone.

ASSAY FOR PURITY
Relative density (V.6.4): 0.968 - 0.978.

Dry residue (V.6.22.N2): Not less than 0.15 per cent.

STORAGE
Protected from light.